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7.0 510(k) Summary

NOV 16 2005

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500, ext. 2367

Contact: Christine Ford, Sr. Regulatory Affairs Analyst

DEVICE NAME:

Contrast Media Transfer Sets
CT Transfer Set, Cath Lab Transfer Set, Cath Lab Extension Set

COMMON OR USUAL NAME:

Fluid Transfer Set

DEVICE CLASSIFICATION:

Class II per Code of Federal Regulation, Title 21, §892.1600, Angiographic X Ray System, product code IZI and §880.5440, Intravascular administration set, product code LHI.

PREDICATE DEVICE:

B. Braun Medical, Inc.
Contrast Media Set, K955179

North American Instrument Corporation
NAMIC Contrast Savings Delivery System, K903493

Merit Medical Systems, Inc.
Contrast Management Systems, K961794

DESCRIPTION:

The Contrast Media Transfer Sets are intended to be used for the transfer of contrast media from a primary supply container to a secondary unit. These sets will allow for multiple unit doses from the same contrast media primary container. The three sets include the CT Transfer Set, the Cath Lab Transfer Set and the Cath Lab Extension Set.

The CT Transfer Set consists of a vented dual-flow spike at the primary source connection end and tubing that runs from the spike to an Ultrasite® luer lock needle-free access valve.

The Cath Lab Transfer Set consists of a vented dual-flow spike at the primary source connection end, a burette chamber which is designed with a stopcock and air inlet filter that allows for priming of the burette, and a second tubing segment that leads from the burette chamber to an Ultrasite® valve. The burette is designed with an auto-shutoff disk which inhibits air from entering the set when the primary contrast media container is depleted.

A Cath Lab Extension Set, which is available as a single patient use extension device, is attached to the Cath Lab Transfer Set at the Ultrasite valve. The Cath Lab Extension Set is equipped with two backcheck valves. In a clinical setting, following connection to the Cath Lab Transfer Set, the extension set is connected to a manifold which allows for the dispensing of multiple doses of contrast media to the patient during the cath lab procedure. Attachment of a new Cath Lab Extension Set to the Cath Lab Transfer Set for each patient allows for dispensing from the same bottle of contrast media to multiple patients.

INTENDED USE: The Contrast Media Transfer Sets are intended to be used for the transfer of contrast media from a primary supply container to a secondary unit. These sets will allow for multiple unit doses from the same contrast media primary container.

SUBSTANTIAL EQUIVALENCE: The Contrast Media Transfer Sets have the same intended use, operation and function as stated for the Contrast Media Set distributed by B. Braun Medical, Inc., K955179, Contrast Savings Delivery System distributed by NAMIC, K903493, and Contrast Management System distributed by Merit Medical Systems, Inc., K961794. There are no differences that raise new issues of safety and effectiveness.

8.0 Attachments

Attachment I:	Proposed Device Labeling
Attachment II:	Device Drawings
Attachment III:	Material Biocompatibility
Attachment IV	Predicate Device Labeling and Information
Attachment V:	Performance Test Data
Attachment VI:	Risk Analysis
Attachment VII:	Samples

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2005

Ms. Christine Ford
Senior Regulatory Affairs Analyst
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109

Re: K052252
Trade/Device Name: Contrast Media Transfer Sets
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: August 16, 2005
Received: August 18, 2005

Dear Ms. Ford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K052252

2.0 Indications for Use Statement

510(k) Number (if known): K052252

Device Name: Contrast Media Transfer Sets

Indications For Use:

The Contrast Media Transfer Sets are intended to be used for the transfer of contrast media from a primary source container to a secondary unit. These sets are intended to allow for multiple unit doses from the same Contrast Media primary container.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K052252